

## REMARKS

Reconsideration of this application is respectfully requested in view of the foregoing amendment and the following remarks.

Claims 3, 4, and 8-19 were pending in this application. In this Amendment, Applicants have amended claims 3, 4, 8, 10, and 12, and have canceled claims 9 and 11. Accordingly, claims 3, 4, 8, 10, and 12-19 will be pending upon entry of this Amendment.

In the final Office Action mailed December 26, 2007, claims 12 and 17-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,613,064 to Rutynowski et al. ("Rutynowski") in view of U.S. Patent No. 5,871,494 to Simons et al. ("Simons"). Claims 3-4, 8-11, and 13-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rutynowski in view of Simons, and further in view of U.S. Patent No. 6,558,402 to Chelak et al. ("Chelak"). In the Response to Arguments section, at page 7 of the Office Action, the Examiner also generally cited U.S. Patent No. 7,087,068 to Marshall et al. ("Marshall") as disclosing a lancing device comprising a force adjusting member that adjusts lancing force. To the extent that the rejections might still be applied to the currently pending claims, Applicants respectfully traverse the rejections.

Initially, Applicants respectfully disagree with the Examiner's continued assertion that Simons teaches control of the lancing force. As explained in detail in the Request for Reconsideration filed June 11, 2007, Simons' teachings are limited to adjustment of the puncture depth and the preload force applied to the skin *before* lancing. From the description and drawings of Simons, it is clear that the drive spring 552 can be compressed only at a single non-

adjustable distance, thereby providing only one non-adjustable force at which the tip 216 is propelled. The lancing force of the Simons device therefore is not adjustable.

Significantly, the portions of Simons to which the Examiner cited on page 7 of the Office Action are merely broad statements in Simons that allege some type of lancing force control, without any reference to components of the Simons device that actually provide that control function. Indeed, the Examiner did not cite to any further explanation of structure or function in Simons that supports the notion that the Simons device controls lancing force, as the Examiner claims. In fact, to the contrary, as explained in the previously filed Amendment, the sole concern of Simons is regulating puncture depth, which is affected by both the distance by which the lancet 216 extends from the test cartridge 210 (adjustable by depth adjuster 560) and also the preload force as it affects the tautness of the skin (adjustable by force adjuster 528). In this manner, Simons fails to provide an enabling disclosure for the subject matter for which the Examiner applies it. "The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003); MPEP §2121.01.

Applicants therefore respectfully submit that previously pending independent claims 3, 4, and 12 are patentable over Simons. Nevertheless, to advance prosecution of this application, Applicants have amended independent claims 3, 4, and 12 (and dependent claims 8 and 10, for consistency) to clarify features of the present invention distinguishable over the prior art of

record. In particular, the amended independent claims recite that: (1) in the first stable position (*i.e.*, initial biasing position), the distance in which the drive spring is held does not change when the puncturing force adjusting member changes the puncturing force; and (2) in the device of the present invention, the puncturing depth and puncturing force are independently adjustable.

Regarding the first feature, independent claim 12 (and similarly independent claims 3 and 4) recites that the adjustable push element is configured to change a second distance between the member that presses the piston and the piston, without changing a first distance between the adjustable push element and the piston, in which the drive spring is held in the first stable position. In other words, as the adjustable push element adjusts the distance in which the drive spring is to be compressed in the operational position when the piston is pressed by the member of the adjustable push element, the initial biasing tension of the drive spring, as defined by the distance between the adjustable push element and the piston, *remains constant*. For example, as shown in Figure 4 of the present application, the distance between the face 9 of the push element 2 and the piston 5, in which drive spring 10 is compressed, remains constant as the setting element 38 is turned to change the distance in which the drive spring 10 is to be compressed when push element 2 is pushed and the member 39 contacts the piston 5 in the operational position. Keeping the drive spring at a constant initial biasing tension in the first stable position can ensure a longer life and better operation of the drive spring by avoiding unnecessary prolonged compression that can cause a reduction in the force applied by the spring in operation. In this manner, the drive spring is compressed only when it is about to be used.

The prior art of record lacks this constant initial biasing tension. For example, the Marshall reference that the Examiner cited informally as teaching the concept of adjusting lancing force changes the initial biasing tension, and keeps the spring at the initial biasing tension until the device is used. (Column 3, lines 35-37 and column 4, lines 12-20.)

Regarding the independent adjustment of the puncture force and depth, the amended independent claims each recite a push element and puncture depth element. As described above, the push element can adjust the distance between the piston and the member of the push element that presses the piston to control the puncture force. On the other hand, the puncture depth element can change the ending position at which travel of the piston is stopped. The puncture depth element can change the ending position without affecting the distance adjusted by the push element, and in turn, the push element can change that distance without affecting the ending position. Figures 1, 4, and 6 illustrate these adjustments, for example. In this manner, the present invention provides a fully customizable lancet that can accommodate any combination of desired puncture depths and forces. The prior art devices fail to teach or suggest this independent adjustment of puncturing depth and puncturing force.

The independent adjustment feature of the present invention provides decided advantages in accommodating the varying skin and bleeding characteristics of users. For example, a user with delicate skin and weak bleeding may need a lesser puncturing force at a greater puncturing depth. Prior art devices, however, tend to allow only upward or downward adjustment of both force and depth. Thus, the prior art devices can cause a high degree of pain and effusions, which can in turn render the healing of the skin puncturing place difficult and thereby prevent further

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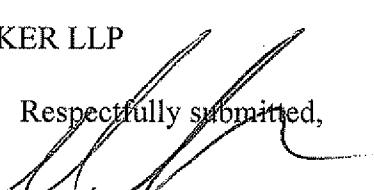
desired sampling in the vicinity of that puncturing location. Similarly, in case of a user with the hard skin and profuse bleeding, the prior art devices may undesirably effuse a significant amount of blood because the greater puncturing force required to break the hard skin also requires a greater puncturing depth, which is not necessary for a user having good bleeding characteristics. The deep puncture can thereby unnecessarily cause trouble with healing of a wound and formation of concretions/adhesions. Addressing these drawbacks of prior art devices, the puncturing device of the present invention enables the possibility of separate adjustment of depth and force, to accommodate individual needs due to varying skin and bleeding characteristics.

Applicants therefore respectfully submit that independent claims 3, 4, and 12 are patentable over the prior art of record. In addition, Applicants further respectfully submit that dependent claims 8, 10, and 13-19 are also patentable due at least to their dependence on an allowable base claim and for the additional features recited therein.

In view of the foregoing, all of the claims in this case are believed to be in condition for allowance. Should the Examiner have any questions or determine that any further action is desirable to place this application in even better condition for issue, the Examiner is encouraged to telephone Applicants' undersigned representative at the number listed below.

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